

REMARKS

Claims 2, 3, 6, 7, 10-12, 14-21, 38, 40-43, 45, 51-54, 56, 60, 61, 63, 64, 66-73 and 75-85 are pending in the application, claims 41, 43, 82 and 83 are withdrawn from consideration. By the October 17, 2006 Office Action, claims 2, 3, 6, 7, 10-12, 14-21, 38, 40, 42, 45, 51-54, 56, 60, 61, 63, 64, 66-73, 75-81, 84 and 85 stood rejected. By this amendment, each of the independent claims, claims 38, 63, 64 and 73, have been amended to more clearly and succinctly define their invention. By the appended Declarations, Applicants have set forth test data and/or established the “skill of one of ordinary skill in the art” in support of their invention and in rebuttal to the arguments presented in the prosecution of this application to date. Once again, Applicants have duly considered the references and arguments put forth by the Patent Office but do not believe prima facie obviousness has been established or, in the alternative, believe that any allegation of prima facie obviousness has been fully rebutted as set forth below.

Claim Amendments

Independent claims 38, 63, 64 and 73 have been amended to specifically recite that the hydrophilic polymer is “a **water absorbing, water vapor absorbing and wettable** hydrophilic polymer” in following with Applicants’ definition of hydrophilic at page 7, lines 6-7, as filed (Paragraph 0032 as published in US 2003/0118664A1). No new matter is entered.

Claim Rejections

JP 4-66512 – Hydrophilic or Hydrophobic

In looking back at the lengthy prosecution of this patent application, the most crucial element of the patent examiner’s continuing rejection has been his conclusion, and reliance upon that conclusion, that the polyurethane employed in JP 4-66512 is hydrophilic. Although the examiner has couched his conclusion in terms of asserting that JP 4-66512 does not specifically preclude the use of a hydrophilic polyurethane and, in following, that Applicants have not proven that it is not hydrophilic: the underlying theory can only be a belief or conclusion on the part of the examiner that the polyurethane is or may be inherently hydrophilic.

As set forth in MPEP 2112, in order to establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ In re Robertson, 169 F3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex Parte Levy, 17 USPQ2d 1461, 1464 (Bd Pat App & Inter 1990). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada 911 F2d 705, 709, 15 USPQ2d 1655, 1658 (Fed Cir 1990)

Contrary to the requirements for establishing inherency, no such “basis in fact and/or technical reasoning” in support of the allegation of hydrophilicity of the polyurethane has been provided or established. Instead, as noted above, it appears that the examiner has merely taken the approach that it is incumbent upon Applicants to disprove the assertion of inherency, even in the absence of any proof or suggestion as to the possibility of such inherency.

Regardless, even if the examiner had provided support to establish a prima facie case, in their past several responses, Applicants have presented concrete arguments in contradiction to the examiner’s position, yet, such arguments have seemingly fallen on deaf ears with the examiner continuing with the position that Applicants have not proven that the polyurethane in JP 4-66512 is not hydrophilic. In part, the examiner has relied upon different test methods employed in the cited art for determining water absorbing properties asserting that since Applicants and JP 4-66512 did not use the most extreme testing method, we have not necessarily proven our case.

MPEP 2112 clearly states that a prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). In reiteration of and in further support of their arguments that not only is the polyurethane of JP 4-66512 **not necessarily**, but is

in all likelihood not, hydrophilic, Applicants herewith submit the appended Declarations of Drs. Trogolo and Rossitto. These Declarations are proffered as testaments to the state of the art and the ordinary skill of the art as well as experimental proofs as to the actual nature, or at least the most likely nature, of the polyurethane of JP 4-66512. While the ultimate proof would have been to secure a sample of the polyurethane employed in JP 4-66512 or the materials needed to make the same, multiple efforts by the undersigned and Dr. Rossitto to contact the last known supplier of these materials have gone without response. Similarly, diligent efforts to identify any details of these materials through numerous internet searches have proven unfruitful. Regardless, the evidence and arguments set forth in the Declarations amply and resoundingly rebut any allegation of inherent hydrophilic properties, as further discussed below.

Dispersability

As discussed in both Declarations, the difficulty in dispersing hydrophilic particles, particularly hydrophilic inorganic particles, in hydrophobic resins is well known in the art. Indeed, this is one of the very problem being addressed by JP 4-66512, i.e., improving the dispersability of the hydrophilic zeolite in a hydrophobic resin. This difficulty is typically associated with an agglomeration of the hydrophilic particles owing to their hydrophilic nature and/or adsorbed/absorbed water. In order to overcome this problem, it is equally well known to change the surface characteristics/properties of the particles so as to present a non-hydrophilic surface by altering the existing surface chemistry through a chemical reaction or by physically masking the surface by the application of a coating. Both methods involve the use of hydrophobic materials. While the most common method in the art involves the use of silanes and other silicon materials as a surface treatment, as noted in JP 4-66512, hydrophobic polymers can also be used.

The examiner suggests that a hydrophobic polyurethane is not needed and that one could just as likely use a less hydrophilic polyurethanemer; yet, provides no basis for such a statement nor any direction as to how much hydrophilicity would be allowed before the objective of JP 4-66512 is completely or effectively frustrated. To some extent, the examiner's position is correct; though not in the manner suggested. Specifically, as discussed in the Declarations, hydrophobicity

and hydrophobicity are properties or characteristics of degree. Thus, many polymers that are hydrophobic have some minimal water content or water content capability: this may be the reason the polyurethane of JP 4-66512 manifested a water content, but did not gain water weight when left out overnight. This does not, however, make them hydrophilic within the meaning and scope of Applicants' claims.

Specifically, Applicants have amended the claims to recite that the hydrophilic polymer must have a water absorption capability of at least 5 wt % and must be "water absorbing, water vapor absorbing and wettable." In contrast, JP 4-66512 specifically calls for polyurethanes that are not hygroscopic and further demonstrates a polyurethane whose water content is less than 5 wt%. Indeed, it may well be much lower if not non-existent since the water mentioned may be that attributed to the zeolite particle. Regardless, it is clear that the hydrophilic called for by the claims of the present invention are distinct from and taught away from by JP 4-66512.

Furthermore, while a polyurethane of low water content may be used, as shown by JP 4-66512, JP 4-66512 makes clear that it be non-hygroscopic. This is consistent with the desirability of avoiding surface moisture and/or affinity for water: the elements responsible for agglomeration and dispersion problems. Thus, while Applicants believe the broad independent claims are distinguishable on their own, certain of Applicants' dependent claims indicate that the water absorption capability be at least 20 wt%. As shown in the Declaration of Dr. Trogolo (see Water Absorption Study #1), 20 wt % is also the general water absorption capability of the silver zeolites themselves. Certainly, then, one would not use a hydrophilic polyurethane whose water absorption characteristics are no different from the hydrophilic particle in order to improve the latter's dispersability in a hydrophobic resin. Yet, such would be the case if Applicants' preferred hydrophilic polymers were used. Thus, it is seen that Applicants' claims do not overlap with the teaching of JP 4-66512 and in fact teach away from the teaching of JP 4-66512. Simply stated, it would be counterintuitive and counterproductive to modify the silver zeolite in a way that knowingly preserves the very problem being addressed; even if the problem were lessened to a degree, where a complete solution is readily available by use of hydrophobic materials.

Thus, considering the dispersability factor, all logic suggests and points to the polyurethane of JP 4-66512 as being hydrophobic.

Water Vapor Absorption

In past Office Actions the examiner has questioned Applicants' arguments relative to the hydrophilicity of the polyurethanes, including that of JP 4-66512, on the basis that the conditions for testing or evaluating water uptake were not appropriate and that such a determination must be conducted in a 100% humidity environment or by immersion. While this may be the proper way to assess the ultimate or maximum water absorption capability of a material, it does not mean that hydrophilicity and hydrophilic characteristics cannot be assessed in less humid environments. Indeed, as discussed in both of the attached Declarations, hydrophilic materials, especially strongly hydrophilic materials, will endeavor to reach equilibrium with its environment. Thus, so long as a hydrophilic polymer is not at water equilibrium with its environment and moisture/water is available, the polymer will seek to absorb water: some more efficiently than others.

In support of the foregoing, Applicants address the examiner's attention to that portion of the Trogolo Declaration entitled "Water Absorption Studies #s 2 and 3" and Table 6 thereof. There, the water absorption characteristics of hydrophilic and hydrophobic polyurethanes are evaluated in both low and high humidity environments. As seen, the only difference in water absorption properties of a hydrophilic polymer in low and high humidity environments is the rate and amount of water uptake. In both environments, readily detectable water gain was noted even in a short period of time. It is further interesting to note that the hydrophobic polyurethanes also manifested a minor water uptake. This finding is consistent with a hydrophobic polyurethane having a low water absorption capability that had been dried during the curing process. However, more important is the significant increase in water absorption of the hydrophilic polymer even though it is the same polyurethane but modified by the inclusion of a small amount, 20 wt%, of the PVP. Certainly, if the polyurethane of JP 4-66512 were hydrophilic, one would have expected detectable water gain.

Further supporting this conclusion and in contrast to the position of the examiner is the fact that JP 4-66512 initially and purposely leave their zeolites out overnight to absorb moisture before encapsulating the same with the polyurethane. If, in fact, there were no or very low humidity, there would have been no basis for such a process step. Further still, if the polyurethane were hydrophilic one would have expected a noticeable weight gain if not on the basis of the polymer then on the basis of the zeolite. Specifically, the polymerization process for the polyurethane of JP 4-66512 was of such temperatures and duration (150°C for > 20 minutes) as to have been sufficient to drive moisture out of the zeolites. The strongly hygroscopic nature of the zeolites would have endeavored to reabsorb any lost moisture if reabsorption were possible. The fact that none was detected suggests quite convincingly, that the polyurethane coating prevented water absorption by the zeolite: a happenstance consistent with a hydrophobic polyurethane, certainly not a hydrophilic polyurethane.

Even if moisture was not lost from the zeolites during polymerization or that such loss had been accounted for in the data presented in JP 4-66512, one would have expected the water content for the two samples, i.e., the 1.5 wt% encapsulated and the 3 wt% encapsulated silver zeolites, to have been the same or, though marginally detectable, greater for the latter since more polymer was present. However, as seen in Table 2 of JP 4-66512, the latter contained substantially less water. This is consistent with the use of a hydrophobic polyurethane on at least two counts. First, adding more of a non-water containing material to a water containing material will reduce the overall water content as the total water weight is divided by a higher total weight. Second, the only other way to account for the water drop is that water had been driven from the zeolite during the coating process and the polyurethane coating actually served as a barrier preventing water from reabsorbing into the zeolite particle.

Thus, based on these comparative studies and the specific teachings and results presented in JP 4-66512, once again, all factors point to the conclusion that its polyurethane was hydrophobic.

Ion Release

As set forth in Table 2 of JP 4-66512 and as noted in both Declarations, the coated particles of JP 4-66512 manifested a marked drop in ion release (~35% drop) merely as a result of increasing

the coating thickness of the polyurethane polymer by about 0.05 microns. Such a dramatic drop in ion release, particularly with such a small increase in coating thickness can only point to a coating that is precluding the release of ions. Since a hydrophilic polymer would readily allow for the passage of ions, particularly with such a thin layer of material, the only possible conclusion is that the polyurethane used to coat the particles is a hydrophobic polyurethane.

As further support for this conclusion, the examiner's attention is directed to the results presented in Table 3 of the Trogolo Declaration. There, it is seen that the encapsulation of the silver zeolite in a hydrophobic polyurethane reduced the ion release as compared to the use of a neat silver zeolite, i.e., without any coating. Though we do not know what the release would have been had JP 4-66512 employed the neat silver zeolite, the reduce ion release with thicker coatings amply suggests that the coating would have reduced the release as compared to the neat silver zeolite. These results are in sharp contrast to those obtained with the compositions prepared in accordance with the present invention. Specifically, a marked increase in ion release was manifested in those compositions wherein the silver zeolite was coated with a hydrophilic coating (Example 5) as compared the the neat silver zeolite or a hydrophobic polymer coated silver zeolite. Similar results are also clearly presented in the application as well as in Applicants' corresponding equivalent PCT patent application (WO 03/055941).

Thus, based on the ion release properties of the reference in light of the comparative study, the only conclusion is, once again, that the polyurethane of JP 4-66512 is hydrophobic.

Chemistry

Finally, as discussed in the Declarations, hydrophilic polyurethanes represent but a small subset of the myriad of the known and commercially available polyurethanes. Since polyurethanes are typically hydrophobic, hydrophilicity is achieved by either combining the polyurethane precursors with a hydrophilic polymer that is substantially miscible therewith (e.g., PVP) or by incorporating hydrophilic segments into the polyurethane polymer. Since JP 4-66512 does not speak of adding a hydrophilic polymer, any hydrophilic characteristic of the JP 4-66512 polyurethane would have to have been derived from the co-reactants for the polyurethane itself. As set forth in Fischer et. al. and Marans et. al., both of which were cited by the examiner in the

Office Action of October 17, 2006, the preparation of hydrophilic polyurethanes is contingent upon the proper selection of the polyurethane precursors, most notably, the polyol, and, in particular, the presence of a significant amount of polyethylene oxide in the polyol. For example, at Col. 3, line 12, to Col. 4, line 2, Fischer et. al. indicates that water solubility, hence the hydrophilic properties, are attributable to the hydrophilic nonionic groups of the polyethylene ether. However, JP 4-66512 only mentions poly(oxypropylene ether)polyol, poly(oxyethylene propylene ether)polyol, acryl polyol, castor oil derivatives and tall oil derivatives as possible polyol based precursors. Of these, only the poly(oxyethylene-propylene ether)polyol could possibly provide any hydrophilic properties according to Marans et. al. and Fischer et. al. While both Marans et. al. and Fischer et. al. recognize that other diols may be copolymerized with the ethylene glycol, they also make clear that a predominant amount of the polyol must be derived from ethylene glycol in order to impart hydrophilic properties. For example, Fischer et. al. state that “[C]opolymers of ethylene oxide, for example with propylene oxide, may also be used **providing they are sufficiently soluble in water,...**” (See Col. 3, lines 26-30) Clearly, then, not all copolymers, even of ethylene oxide and propylene oxide are hydrophilic. In light of the findings set forth above, the clear presumption is that even if the polyol used in making the polyurethane of JP 4-66512 were a poly(oxyethylene-propylene ether) polyol, there were insufficient ethylene ether segments to provide sufficient hydrophilicity to the polyurethane to meet the claim requirements of and to be useful in the practice of the present invention.

Further support of this conclusion is found in Yashiki - US 4,657,835, which, as discussed in the October 31, 2006 response, prepares a polyurethane resin from an isocyanate and Nippolane 1100 polyol, the same polyol used in JP 4-66512. While Yashiki does not specifically identify the polyurethane as hydrophobic, as noted in Col. 1, lines 26-61, one of the key and critical requirements of the polyurethane is its electrical properties, particularly electrical resistance. Specifically, Yashiki states that “...**electrical resistance is required to be unaffected by environmental changes, particularly by the changes in atmospheric humidity.**” (Col. 1, lines 43-45 – emphasis added) Inasmuch as hydrophilic polyurethanes, particularly ones that are “water absorbing, water vapor absorbing and wettable,” tend to be extremely sensitive to and subject to change by atmospheric humidity, they would not be suitable for use in Yashiki. Thus,

once again, one must conclude that the polyurethane of JP 4-66512 is not hydrophilic, at least certainly not within the context of the claims of the present invention.

Summary

As discussed above and in the Declarataions and as demonstrated by the experiments set forth in the Trogolo Declaration, Applicants have shown by a preponderance of evidence that the polyurethane employed in JP 4-66512 is or is at least most likely to have been a hydrophobic polyurethane. No other conclusion is reasonable and, consequently, to the extent a prima facie case as to the inherent properties had been established, it is fully rebutted and unfounded.

Release Properties

Rate of Release

Another key argument put forth by the examiner in rejecting Applicants' claims is the premise that one skilled in the art would expect that the addition of a hydrophilic resin together with a silver zeolite antimicrobial agent into a hydrophobic resin would lead to an increase in the rate of ion release in light of the art teaching a higher rate of ion release in hydrophilic polymers. The theory seems to be based on the known method of imparting hydrophilic characteristics to an otherwise hydrophobic polymer by the addition thereto of hydrophilic additives and polymers. While this is in part true, it is not so in the context of the present invention as demonstrated in that section of the Trogolo Declaration entitled "Hydrophilic Modification: Encapsulation v. Matrix Modification."

Specifically, in the Declaration, a hydrophilic polyurethane was made by adding 20 wt% of a hydrophilic polymer (polyvinylpyrrolidone (PVP)) to a curable hydrophobic polyurethane composition and then using that composition to produce polymer particles (PU2) as well as encapsulated silver zeolite particles in accordance with the present invention (ME2). Like polymer particles (PU1) and encapsulated silver zeolite particles (ME1) were also made using the neat hydrophobic polyurethane. As seen in Table 3, the addition of the PVP clearly rendered the previously hydrophobic polyurethane sufficiently hydrophilic so as to enable the release of the metal ions (compare Example 3 with Example 5, Table 3). Indeed, surprisingly, the

encapsulation of the silver zeolites with the hydrophilic polymer resulted in an 80% increase in ion release when added to a hydrophobic epoxy matrix, even as compared to the use of an equivalent amount of the neat, unencapsulated silver zeolite. In contrast, that composition wherein the hydrophilic polyurethane and the silver zeolite were each added as separate components to the hydrophobic epoxy matrix resulted in essentially no difference in ion release or a slightly worsened release than the use of the neat, unencapsulated silver zeolite by itself (compare Example 4 with Example 1, Table 3).

Thus, contrary to the assertion of the examiner, it is not merely a matter of the use of a combination of a hydrophilic polymer and an antimicrobial agent to enhance ion release; rather, as shown by Applicants and the Trogolo Declaration, it is absolutely critical that the antimicrobial agent be incorporated into the hydrophilic polymer prior to its incorporation into the hydrophobic polymer. Furthermore, nothing would have predicted the marked and unexpected improvement in ion release, even as compared to the neat antimicrobial agent, as attained by Applicant when practicing the specific combination/orientation as claimed by Applicants.

Duration of Release

In the Advisory Action the examiner states “[I]t is clear from the prior art that silver ions are soluble in water, as such, the higher the hydrophilicity the higher the elution of the silver. However, the higher the elution of the silver the less duration of activity.” While such may be the expectation, nothing is further from the truth relative to Applicants’ invention. As seen in Example 6 and Figure 4 of Applicants’ corresponding International PCT Patent Publication WO 03/055941 and in Table 1 of the Trogolo Declaration, ion release from the neat silver zeolite when incorporated into a hydrophobic resin is rapid and of relatively short duration, i.e., the silver reservoir is quickly depleted. In contrast, incorporating the same quantity of silver zeolite particles into the same hydrophobic resin wherein the particles are encapsulated in a hydrophilic polymer has both rapid ion release and markedly longer duration as seen in the aforementioned Example of the PCT application as well as in Table 2 of the Trogolo Declaration. This result is especially relevant to those embodiments of the present invention wherein multiple particles of

the antimicrobial agent are dispersed in a single hydrophilic polymer particle: a concept not contemplated by JP 4-66512.

And, while the same longevity and total ion release are not likely to be seen in Applicants' second embodiment wherein, like JP 4-66512, individual particles of the silver zeolite are separately coated; nevertheless, a markedly longer duration and higher total quantity of ion release occurs as compared to the coated particles of JP 4-66512. Specifically, as shown and discussed in AgION Technical Memo #9, submitted on November 15, 2005 ("AgION TM-9") and as further demonstrated in that section of the Trogolo Declaration entitled "Particle Size Effect," increasing the particle size of the antimicrobial agent increases the likelihood that any given particle will be exposed to the surface so as to participate in ion release. Although both AgION TM-9 and the experiments in the Trogolo Declaration relate to hydrophilic polymer particles having multiple silver zeolite particles dispersed therein, the general premise of increasing particle size still holds true as this is a physical phenomenon related to size not make-up of the particles.

As specified in Applicants' claims, that embodiment of Applicants' invention wherein the antimicrobial particles are individually coated with the hydrophilic polymer requires a coating thickness of at least 1 micron which corresponds to a particle that is at least 288% larger (by volume), based on a 3.5 micron silver zeolite, than the uncoated silver zeolite particle. This contrasts sharply with the coated particle of JP 4-66512 which only discloses coating thicknesses on the order of 0.08 microns and less: a thickness that corresponds to coated particles that are only about 14% larger than the neat zeolite. Clearly, any increase in the likelihood that the particles of JP 4-66512 would touch the surface of the polymer into which they are incorporated would be negligible, if detectable, as compared to that to be seen with like compositions made in accordance with the present invention. And, since more particles will be available to provide antimicrobial ions, the compositions of the present invention will also have a greater total ion release as compared to the compositions of JP 4-66512 even though both compositions would have the same total quantity of ions incorporated into the polymer matrix.

Finally, it is acknowledged, as argued by the examiner, that JP 4-66512 allows for the use of more or less polyurethane than set forth in its specified range of 0.1 to 5 % by weight. However, contrary to the implication of the examiner, this is not an open teaching or instruction to use more and more polyurethane, thus thicker and thicker coatings. Rather, JP 4-6651 specifically states that the variation on the amount of the polyurethane to be used **"varies depending upon the particle sizes of an antimicrobial agent particles."** (Emphasis added) This only makes sense since the use of antimicrobial agents of larger and larger particle size will require the use of more and more polymer to coat the particle and even more so to achieve the same coating thickness. Geometry tells us that the surface area to be covered increases on an exponential basis with the increase in radius of the antimicrobial agent particle, i.e., surface area = $4\pi r^2$. In following, unless the amount of coating material is markedly increased, the thickness of the coating decreases on an exponential basis as the particle size increases as shown by the following formula: coating wt = $4/3\pi D[(r_t + r_p)^3 - r_p^3]$ where r_t is the thickness of the coating, r_p is the radius of the antimicrobial particle, and D is the density of the polymer coating material.

Even at the levels demonstrated in JP 4-66512, the coatings are already fractions of a micron in thickness. Hence, any notable increase in the particle size of the silver zeolite without a sufficient increase in the amount of the coating material to be applied thereto will result in coatings that are of insufficient thickness to adequately mask the hydrophilic properties, particularly if the amount of coating material is so low as to result in a discontinuous coating. Consequently, the desired effect and very objective of JP 4-66512, i.e., masking over the hydrophilic properties of the zeolite particle, will be lost. Furthermore, based on the discussion above and the results shown in JP 4-66512 itself, merely increasing the thickness of the hydrophobic coating will only result in increased loss of ion release, if not the cessation of ion release altogether. Thus, JP 4-66512 requires a delicate balance of coating thickness to ensure adequate masking of the hydrophilic properties while concurrently not impeding or precluding ion release. Such is not an issue with Applicants' antimicrobial additives.

October 17, 2006 Art Rejections

Applicants hereby specifically reiterate and incorporate by reference the remarks made in the prior response dated October 31, 2006 and hereby request that the examiner review and reconsider those arguments and discussions in further light of the foregoing and the following supplemental remarks.

Before addressing the rejections specifically, the undersigned wishes to advise the examiner of an inaccurate statement in the prior response. Specifically, in the first full paragraph on page 15 and elsewhere relating to the discussion of JP 4-66512 in the October 31, 2006 response, the undersigned suggested that water absorbed by the zeolites was used, in conjunction with heat, to polymerize the polyurethane. A closer examination of JP 4-66512 reveals that the actual or at least the primary polymerization mechanism involved heat to unblock the blocked isocyanate groups of the Coronate 2507 to expose the same to the active hydrogen of the polyols. However, as noted in the first full paragraph on page 12 of the translation of JP 4-66512, water may have participated in the polymerization. More importantly, it is to be noted that the reaction conditions (temperature and time) were such that water within the zeolite may also have been driven off during the coating process. In any event, it remains clearly evident that the polyurethane was not a hydrophilic polyurethane as required by Applicants' claims.

It is well established in Patent Law that prima facie obviousness of a claimed invention requires that all the claim limitations must be taught or suggested by the prior art (*In re Royka*, 490 F2d 981, 180 USPQ 580 (CCPA 1988)). Furthermore, while the failure to teach, suggest or motivate a combination is not definitively conclusive of patentability when combining multiple references to establish obviousness, there still must be some objective reason for making the combination in the manner proposed. (See e.g., *KSR International Co. v. Teleflex, Inc.*, 550 US ____ (2007); *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. Appl. & Inter. 1993)). And, when the proposed modification in combining multiple references would be such as to render the prior art invention unsuitable for its intended purpose, the combination is inappropriate. (MPEP 2143.01)

Rejection under 35 USC §103(a) over JP 4-66512, Marans et. al. (US 4,403,083), Niira et. al. (US 5,556,699), and Yukei et. al.

Claims 2, 3, 6, 7, 10-12, 14-21, 38, 40, 42, 45, 51-54, 56, 60, 61, 63, 84 and 85 stand rejected under 35 USC 103(a) as being unpatentable over JP 4-66512, Marans et. al. (US 4,403,083), Niira et. al. (US 5,556,699), and Yukei et. al.

JP 4-66512 is cited as disclosing coating silver zeolite with polyurethane resin prepared by reacting a polyisocyanate with a polyether polyol, such as poly (oxypropylene ether) polyol and a poly (oxyethylene propylene ether) polyol and incorporating the same into thermosetting and thermoplastic resins, including polypropylene.

Marans et. al. is cited as disclosing hydrophilic polyurethane particles having a diameter of from 0.1 to 100 microns which are prepared by adding a resin reactant which contains prepolymer containing polyol and polyisocyanate, dropwise into an aqueous reactant. It is alleged that Marans et. al. also teach the addition of up to 800% of water soluble and dispersible materials, including zeolite, to the aqueous reactant or to the resin precursors to effect a wide distribution of the additive in the finally prepared particle. In performing its evaluation of hydrophilicity, Marans et. al. employ a test wherein the polymer particles are placed in a 100% humidity chamber for 3 days before measuring for the increase in weight.

Niira et. al. is cited as teaching antibiotic zeolites containing silver which further incorporate ammonium ions to prevent discoloration of resins into which they are incorporated.

Yukei et. al. is said to disclose the sodium nitrate increased the elution of silver from silver zeolite and was dose dependent.

The primary premise of the rejection is that JP 4-66512, particularly in light of Marans et. al., teaches the coating of antimicrobial silver zeolites with a hydrophilic polyurethane and, consequently, that, but for the addition of ammonium ions and sodium nitrate, these two references teach each and every element of the claimed invention. Applicants respectfully continue to traverse the rejection as such a conclusion and reasoning is completely at odds with the cited references, particularly JP 4-66512 itself, and is adverse to and not supported by the knowledge of those skilled in the art.

First, relative to JP 4-66512, Applicants have amended each of the independent claims to specifically require that the hydrophilic polymer be “water absorbing, water vapor absorbing and wettable:” a condition that is directly contradictory to the requirement of JP 4-66152 which specifically calls for and recites that its polyurethane is non-hygroscopic (See page 15, “Effects of the Invention”). Second, as shown by the attached Declarations and as discussed at length above, Applicants have shown by a preponderance of the evidence that the polyurethane of JP 4-66512 is not hydrophilic, at least not in the context of the present claims, but is or is most likely to be hydrophobic. Third, Marans et. al. is specific to strongly hydrophilic polymer particles and, while it suggests that zeolites could be incorporated into its polymer particles, there is no specific teaching of the same and certainly no mention whatsoever of antimicrobial zeolites. Thus, looking at the art as a whole, there is no objective reason or basis to combine the two references. Indeed, such a combination would be contradictory to the objectives of each. Specifically, JP 4-66512 employs a hydrophobic material to mask the hydrophilic nature of the zeolite; whereas, Marans et. al. is tasked with a new process for making highly hydrophilic polymer particles. Furthermore, even if such a combination were possible, which it is not, nothing in either reference or their combined teachings would have suggested that the specific combination and construction of Applicants antimicrobial additive particles would, when incorporated into another resin, provide such marked improvement in antimicrobial metal ion release as shown by Applicants. Thus, for all of these reasons, the examiner has failed to establish prima facie obviousness and the claims, as currently amended, are in patentable form.

Inasmuch as independent claim 38 and 63 are patentable over the art, the rejection of dependent claims 17 and 18 in further view of Niira et. al. and of dependent claim 21 in further view of Yukei et. al., is moot. It is well established in patent law that claims dependent upon a patentable independent claim are likewise patentable. Thus, the rejection of claims 2, 3, 6, 7, 10-12, 14-21, 38, 40, 42, 45, 51-54, 56, 60, 61, 63, 84 and 85 over JP 4-66512, Marans et. al., Niira et. al., and Yukei et. al. should be withdrawn and the claims passed on to allowance.

Rejection under 35 USC §103(a) over JP 4-66512 in view of Takebayashi et. al. (US 6,113,936) and WO 94/13726 (Fischer – US 6,399,735)

Claims 64, 66-73, and 75-81 stand rejected under 35 USC 103(a) as being unpatentable over JP 4-66512 in view of Takebayashi et. al. and Fischer.

JP 4-66512 is cited for the reasons set forth above, most notably the allegation that JP 4-65512 discloses silver zeolite coated with a hydrophilic polyurethane.

Takebayashi et. al. is cited for the reasons set forth in the prior Office Action, most notably, as disclosing a method of encapsulating silver zeolite with polyurethane wherein the resultant microcapsules have particle sizes and a weight ratio of polymerizable monomer to silver zeolite in the ranges defined by Applicants.

Fischer et. al. is cited as disclosing hydrophilic polyurethanes prepared by reacting polyols with diisocyanate, which polyurethanes are non-hygroscopic.

It is alleged that the prior art discloses silver zeolite coated with a polyurethane derived from a polyisocyanate and a polyether polyol which may be incorporated into a thermoplastic or thermosetting resin, such as polypropylene resin. It is stated that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose that the thickness of the hydrophilic polymer coating is from about 1 to about 15 microns, with a coated particle size of about 300 microns or less and a weight ratio of antimicrobial agent to hydrophilic polymer of from 1:100 to 1000:100. However, it is stated that the prior art amply suggests the same. As such, it is alleged that it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of antibacterial silver zeolites and hydrophilic polymers ranging within the sizes and thicknesses disclosed would have been effective as antimicrobials and that the incorporation of the same into resins, such as polypropylene, would impart antimicrobial activity. Further it is alleged that one of ordinary skill in the art would have expected that the polyurethane polymer used in JP 4-66512 was hydrophilic despite the fact that the polyurethane did not absorb any water when left out overnight.

Applicants respectfully traverse the rejection and request reconsideration. As discussed above, JP 4-66512 does not disclose or teach hydrophilic polyurethanes as a coating material for silver

zeolites. Since Takebayashi et. al. do nothing to overcome that shortfall, the rejection fails as no case of prima facie obviousness has been established.

Despite the plethora of case law cited by the examiner relating to prima facie obviousness in the case of adjacent, overlapping or encompassed ranges as well as optimization, the fact remains that no showing has been made as to the encapsulation or coating of individual particles of an antimicrobial agent with a hydrophilic polymer, let alone at a thickness of 1 to 15 microns. Furthermore, even if a showing were to be made to a hydrophilic coated antimicrobial particle, it is also well established in case law that prima facie obviousness, even where adjacent, overlapping or encompassed claims are found, may be overcome by a showing of unexpected or synergistic results. Though the Examiner would have us believe that Applicants' claimed ranges are mere optimizations, such a contention is not supported, particularly in light of the marked and unexpected performance as demonstrated in the Trogo Declaration as well as has been discussed and demonstrated through empirical data and models in the several prior responses submitted by Applicants during the course of this patent prosecution, all of which are hereby incorporated by reference. Furthermore, the examiner is reminded that merely increasing the thickness of the coating from about 0.076μ (corresponds to 1.5 wt%) to about 0.08μ (corresponds to 3 wt%) in JP 4-65512 (see Table 2) caused a nearly 35% decrease in eluted silver ions: $26.5\mu\text{g/l}$ versus $17.6\mu\text{g/l}$. If merely increasing the coating thickness 5% provided such a dramatic detrimental effect on ion elution, there is certainly no objective reason for increasing the thickness of the coating to at least 1μ , more than a 10 fold increase in thickness, as required by the present claims. One would surmise that such a coated particle would have no silver elution at all:

In view of the foregoing, it is clear that the Patent Office has failed to establish prima facie obviousness. Fischer et. al. fails to provide any tie between its hydrophilic polyurethanes and the polyurethane of JP 4-66512. Indeed, the use of a hydrophilic polyurethane in JP 4-66512 is contrary to its teaching and objective. Takebayashi et. al., due to its breadth, fails to provide any specific guidance to the claimed compositions or the results attained thereby, regardless of whether the coating materials were or were not hydrophilic. Even if a case of prima facie obviousness were established, it has been fully rebutted in light of the arguments and evidence of

unexpected results as set forth above and in the appended Trogolo Declaration as well as in the prior responses, including the prior Declaration of Jeffrey Trogolo, and in the examples of the application and its counterpart International PCT published application WO03/055941. Thus, the rejection of claims 64, 66-73, and 75-81 should be withdrawn and the same passed on to allowance.

Claims Fees

Inasmuch as no changes have been made to the number of pending claims in the application, no additional claims fees are owed

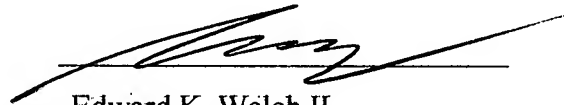
Conclusion

Applicants have shown by a preponderance of information that the polyurethane of JP 4-66512 is not or is most unlikely to be hydrophilic. Without the support of a premise that JP 4-66512 employed a hydrophilic polyurethane, the examiner has no basis upon which to maintain his rejections: there is no objective reason to make the combinations suggested. Instead, looking at the art as a whole and the skill of one in the art, the use of a hydrophilic polymer in the encapsulation process of JP 4-66512 would be contradictory to and completely frustrate the very purpose and objective of that reference. Furthermore, none of the cited art, alone or in combination in any way suggests or predicts the unexpected and superior performance achieved by Applicants' invention. Specifically, neither the teachings of the cited, taken as a whole, nor the level of the skill of the art, even in light of the cited art, in any way supports or makes obvious i) the encapsulation of individual particles of an inorganic antimicrobial agent with a hydrophilic polymer, ii) the preparation of micro-sized particles comprising a hydrophilic polymer having dispersed therein a plurality of particles of an inorganic antimicrobial agent, iii) the use of (i) or (ii) as an antimicrobial additive dispersed in a polymer matrix as a discrete phase, iv) that the compositions of (iii) have markedly and unexpectedly better performance and cost efficiency as compared to similar polymer compositions wherein the antimicrobial agent is not encapsulated with a hydrophilic polymer, etc.

Clearly, the Patent Office has failed to establish prima facie obviousness and, in any event, Applicants have fully rebutted any such claim. Consequently, Applicants believe the claims as currently presented represent patentable subject matter and respectfully request that the rejections be withdrawn and the application passed on to allowance.

In the event that an Office Action is issued before this Supplemental Amendment and Response is passed on to the Examiner, it is respectfully requested that the Office Action be withdrawn. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (781) 718-9512 to discuss the same so that the prosecution of this application can be concluded in favor of issuance of a US Patent.

Respectfully submitted,



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